

## **REMARKS**

After entry of this Amendment, the pending claims are: claims 1-8, 13-21, 23-25, 27, and 53-74. The Office Action dated March 26, 2007 has been carefully considered. Claims 9-12, 22 and 28-52 were previously canceled. Claims 1, 3, 55, and 69 have been amended in this Response. Claims 1, 3, 23, 53, 55, 60, 64, 69, and 72 were amended in the Response dated December 21, 2006. No new matter has been added. Reconsideration and allowance of the present application in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated March 26, 2007, the Examiner considered the Reply to Office Action dated December 21, 2006 to be non-compliant for failing to specifically point out support for the amendments made to the disclosure, including the claims.

### **INDEPENDENT CLAIMS 1 AND 69**

As presently presented, independent claim 1 requires an implant for use in a patient's spinal column, said implant comprising a body portion having a length, a width, and a depth, and configured to be insertable between first and second bone segments, the body portion having an outer surface and an inner surface forming a hollow region, the hollow region comprising most of the volume of the body portion, the body portion further having first and second open ends; wherein at least one of the first and second open ends comprises a single bone receiving channel extending there across that has a first depth measured from the trough of the channel to a first side of the outer surface at the at least one end, the first side extending along the length of the body portion, the channel also having a second depth

measured from the trough of the channel to a second side of the outer surface at the at least one end, the second side extending along the length of the body portion, the second side opposite the first side, the first and second depths having different measurements, the channel configured to engage at least one of the first and second bone segments.

As presently presented, independent claim 69 requires an implant for use in a patient's spinal column, the implant comprising a tubular body having a length, a width, and a depth, and an outer surface and an inner surface forming a thin tubular wall, the perimeter of the outer surface having a substantially oval, circular, or elliptical shape, the body further having first and second open ends; wherein at least one of the first and second ends comprises a single channel extending there across that has a first depth measured from the trough of the channel to a first side of the outer surface at the at least one end, the first side extending along the length of the tubular body, the channel also having a second depth measured from the trough of the channel to a second side of the outer surface at the at least one end, the second side extending along the length of the tubular body, the second side opposite the first side, the first and second depths having different measurements, the channel configured to engage a bone segment.

As an initial matter, after further review, it is believe that the limitation added in the December 21, 2006 Amendment that the body includes first and second ends that define the width and depth of the body portion is not required to distinguish the invention of independent claims 1 and 69 over the cited prior art. Thus, this limitation has been deleted from these claims.

By way of example only, it is respectfully submitted that support for the amendment “the body portion further having first and second open ends” as required by independent claim 1 and the amendment “the body further having first and second open ends” as required by independent claim 69 is contained in, *for example*, Fig. 1A-1C and paragraph 0034. Fig. 1A depicts an implant 1 with first and second ends 6A, 6B. The first and second ends 6A, 6B being depicted with an open end so that the open ends 6A, 6B of the implant 1 are in communication with the inside surface 4 of the implant 1 to define a hollow central region 7. Moreover, paragraph 34 recites:

The implant 1 has a longitudinal axis "CL," a length "L," a wall 5 defining an outside surface 3 and an inside surface 4, and first and second ends 6A, 6B. Inside surface 4 communicates with first and second ends 6A, 6B to define a hollow central region 7 of the implant.

By way of example only, it is respectfully submitted that support for the amendment “wherein at least one of the first and second open ends comprises a single bone receiving channel extending there across that has a first depth measured from the trough of the channel to a first side of the outer surface at the at least one end, the first side extending along the length of the body portion, the channel also having a second depth measured from the trough of the channel to a second side of the outer surface at the at least one end, the second side extending along the length of the body portion, the second side opposite the first side, the first and second depths having different measurements, the channel configured to engage at least one of the first and second bone segments” is contained in Fig. 1C and paragraphs 38 and 39. Fig. 1C depicts an implant 1 with first and second ends 6A, 6B. The first and second ends 6A, 6B including arcuate cut outs 8A, 8B, each of the arcuate cut outs including first and second angle faces 88A, 89A, 88B, 89B. The angle faces 88A, 89A, 88B, 89B meeting at a point, crotch C wherein crotch

C may or may not be coincident with the central longitudinal axis of the implant 1. Each arcuate cutout 8A, 8B further including first and second face depths F1, wherein the first and second face depths are a measure of the depth of the crotch C relative to the inner side region 3B and the outer side region 3A of the implant 1, respectively. The first and second face depths F1, F2 may or may not be the same depending on whether or not the point, crotch C, coincides with the central longitudinal axis of the implant 1. Moreover, paragraph 38 and 39 recite:

[0038] Implant 1 is substantially straight along its length, and so to accommodate this angular displacement of the lamina, first and second ends 6A, 6B incorporate arcuate cutouts 8A, 8B to grasp and retain the cut lamina segments ...

[0039] In the preferred embodiment, shown in FIG. 1C, each arcuate cutout 8A, 8B comprises first angled faces 88A, 89A and second angled faces 88B, 89B, respectively, which meet at crotch "C" to form a face angle "A." ... Each arcuate cutout further comprises first and second face depths "F1" and "F2." The first and second face depths are a measure of the depth of the crotch relative to the inner side region 3B and outer side region 3A of the implant, and will be different lengths whenever the centerline 1a of the arcuate cutout is offset from the centerline "CL" of the implant 1.

Based on the above Remarks, it is respectfully submitted that the amendments to independent claims 1 and 69 are fully supported by the Applicants' specification.

## **INDEPENDENT CLAIMS 23, 53 AND 72**

As currently presented, independent claim 23 requires an implant for use in a patient's spinal column, said implant comprising a body portion having a longitudinal axis and configured to be insertable between first and second bone segments, the body portion having an outer surface and an

inner surface defining a substantially hollow portion, said body portion further having first and second ends open to said hollow portion and orthogonal to said longitudinal axis, said first and second ends comprising concave cutouts configured to engage and retain said first and second bone segments, the cutouts each comprising a centerline running parallel to the implant longitudinal axis and dividing each of the cutouts, wherein the centerline of the cutout of the first end is offset from the implant longitudinal axis in one direction, and the centerline of the cutout of the second end is offset from the implant longitudinal axis in the opposite direction.

As currently presented, independent claim 53 requires an implant for use in a patient's spinal column, said implant comprising a body portion having a length, a width, a depth and a longitudinal axis, and configured to be insertable between first and second cut bone segments, the body portion having an outer surface and an inner surface defining a substantially hollow portion, the body portion further having first and second ends open to said hollow portion and orthogonal to said longitudinal axis, at least one of the first and second ends comprising a cutout configured to engage and retain at least one of the first and second cut bone segments, the cutout comprising a centerline running parallel to the implant longitudinal axis dividing said ends, wherein the centerline of the at least one cutout is offset from the longitudinal axis.

As currently presented, independent claim 72 requires an implant for use in a patient's spinal column, the implant comprising a tubular body having a length, a width, a depth, a longitudinal axis, and an outer surface and an inner surface forming a thin tubular wall, the perimeter of the outer surface having a substantially oval, circular, or elliptical shape, the body further having first and second ends

orthogonal to the longitudinal axis, at least one of the first and second ends comprising a cutout configured to engage and retain a bone segment, the cutout comprising a centerline running parallel to the implant longitudinal axis dividing the ends, the centerline of the at least one cutout being offset from the longitudinal axis.

By way of example only, it is respectfully submitted that support for the amendment “said body portion further having first and second ends open to said hollow portion and orthogonal to said longitudinal axis, said first and second ends comprising concave cutouts,” as required by independent claim 23, support for the amendment “the body portion further having first and second ends open to said hollow portion and orthogonal to said longitudinal axis, at least one of the first and second ends comprising a cutout,” as required by independent claim 53, and support for the amendment “the body further having first and second ends orthogonal to the longitudinal axis, at least one of the first and second ends comprising a cutout,” as required by claim 72 is contained in, *for example*, Fig. 1A-1C and paragraph 0034.

Fig. 1A depicts an implant 1 with first and second ends 6A, 6B. The first and second ends 6A, 6B being depicted with an open end so that the open ends 6A, 6B of the implant 1 are in communication with the inside surface 4 of the implant 1 to define a hollow central region 7. The open ends 6A, 6B being substantially perpendicular (i.e., orthogonal) to the longitudinal axis of the implant 1. In addition, Fig. 1C depicts an implant 1 with first and second ends 6A, 6B. The first and second ends 6A, 6B including arcuate cut outs 8A, 8B. Moreover, paragraphs 34 and 38 recite:

[0034] The implant 1 has a longitudinal axis "CL," a length "L," a wall 5 defining an outside surface 3 and an inside surface 4, and first and second ends 6A, 6B. Inside surface 4 communicates with first and second ends 6A, 6B to define a hollow central region 7 of the implant.

[0038] Implant 1 is substantially straight along its length, and so to accommodate this angular displacement of the lamina, first and second ends 6A, 6B incorporate arcuate cutouts 8A, 8B to grasp and retain the cut lamina segments.

Based on the above Remarks, it is respectfully submitted that the amendments to independent claims 23, 53 and 72 are fully supported by the Applicants' specification.

Support for the amendments made in the December 21, 2006 Reply to Office Action has been presented above by way of example only. Applicants are in no way limiting their invention by pointing out such support. In addition, Applicants do not state that additional support for said amendments do not reside elsewhere in the specification.

**U.S. PATENT NO. 6,436,139 TO SHAPIRO *ET AL.***

For the Examiner's benefit, a recitation of the Remarks from the Applicants' Reply to Office Action dated December 21, 2006 is reprinted herein.

**Rejections of Claims Under 35 U.S.C. § 102(c)**

Independent claims 1, 23, 53, 69, and 72 and dependent claims 2, 5, 6, 15-21, 24, 25, 54, 56, 58, and 63-68 were rejected under 35 U.S.C. § 102(c) as being anticipated by Shapiro.

These rejections are respectfully traversed.

Shapiro does not anticipate applicants' invention as claimed.

Amended independent claims 1 and 69 each require the single channel to extend across an open end of the body portion. Shapiro's thread cutouts 14 and 20 (*see* Shapiro's FIGS. 1-3), which the Examiner equated to applicants' channel, do not extend across an open end of Shapiro's interbody fusion device 10. Furthermore, thread cutouts 514 and 520 (*see* Shapiro FIG. 12), which the Examiner also equated to applicants' channel, also do not extend across an open end of Shapiro's fusion device 510.

Amended claims 1 and 69 also require the channel to have different depths as measured from opposite sides of the trough (*see* applicants' FIG. 1C, noting face depths F1 and F2). Shapiro plainly has no such channel on either its first or second end 34 or 36, respectively. In particular, Shapiro's FIGS. 1, 2, 4A, 4B, and 4C show no channel extending across second end 36 and a symmetrically-shaped tool driving slot 16 extending across first end 34. Slot 16 does not have different first and second depths (as best seen in FIG. 4B). Moreover, concave sidewall 24, even if arguably considered to be a channel extending across an arguably open end (window 38), is also symmetrically shaped and does not have different first and second depths (as best seen in FIG. 5A).

Accordingly, independent claims 1 and 69 are not anticipated by Shapiro.

Amended independent claims 23, 53, and 72 each require first and second ends to be orthogonal to the longitudinal axis (*see, e.g.,* first end 6A, second end 6B, and longitudinal axis CL in applicants'



FIGS. 1A and 1C). These claims also require at least one end to have a cutout comprising a centerline running parallel to the longitudinal axis (*see, e.g.*, centerline 1a in FIG. 1C).

Shapiro's thread cutouts 514 and 520 (*see* Shapiro FIG. 12), which the Examiner equated to applicants' cutout, "are formed along line 570, which runs substantially parallel to ... longitudinal axis 19" (Shapiro column 8, lines 20-22). Thus, line 570 extends along a side of fusion device 510 that is parallel, not orthogonal, to longitudinal axis 19. Therefore, that side of device 510 does not meet the claimed limitation of applicants' first or second ends, which are required to be orthogonal to the longitudinal axis and, accordingly, thread cutouts 514 and 520 do not meet the claimed limitations of applicants' cutout.

Independent claims 23, 53, and 72 are thus not anticipated by Shapiro.

For at least the above reasons, dependent claims 2, 5, 6, 15-21, 24, 25, 54, 56, 58, and 63-68 should also not be anticipated by Shapiro (i.e., dependent claims are patentable if their independent claim is patentable).

Accordingly, applicants respectfully request that the rejections of claims 1, 2, 5, 6, 15-21, 23-25, 53, 54, 56, 58, 63-69, and 72 under 35 U.S.C. § 102(e) be withdrawn.

Rejections of Claims Under 35 U.S.C. § 103(a)

Dependent claims 3, 4, 7, 8, 13, 14, 27, 55, 57, 59-62, 70, 71, 73, and 74 were rejected under 35 U.S.C. § 103(a) as being obvious from Shapiro.

These rejections are respectfully traversed.

For at least the reasons discussed above with respect to amended independent claims 1, 23, 53, 69, and 72, dependent claims 3, 4, 7, 8, 13, 14, 27, 55, 57, 59-62, 70, 71, 73, and 74 should no longer be obvious from Shapiro (i.e., dependent claims are patentable if their independent claim is patentable).

Accordingly, applicants respectfully request that the rejections of claims 3, 4, 7, 8, 13, 14, 27, 55, 57, 59-62, 70, 71, 73, and 74 under 35 U.S.C. § 103(a) be withdrawn

## CONCLUSION

Withdrawn of the Office Communication dated March 26, 2007 and consideration of the attached claims and remarks is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Date: April 25, 2007

Respectfully submitted,

/Giuseppe Molaro/  
Giuseppe Molaro  
Registration No. 52,039

For: Brian M. Rothery  
Registration No. 35,340

Attorney for Applicants  
Stroock & Stroock & Lavan LLP  
180 Maiden Lane  
New York, New York 10038  
(212) 806-6114